

## B. Remarks

The numbered paragraphs below correspond to the numbered paragraphs of the Official Action. The Applicant respectfully requests reconsideration in light of the present remarks.

2. In response to the Examiner's rejection of Claims 19 and 20 for alleged indefiniteness under 35 U.S.C. § 112, second paragraph, the Applicant respectfully traverses. The phrase, "the active ingredient and the linker form a substituent" on the polymer, in both claims is clear on its face. The phrase is also clear in light of sole independent Claim 15, from which Claims 19 and 20 ultimately depend. The relevant portion of Claim 15 reads, "an active ingredient covalently bonded to a linker . . . said linker being covalently bonded to . . . a crosslinked polymer . . . ."

An artisan skilled in the chemical arts would realize at a glance the exact meaning of the phrase and how to replicate the delivery system. If any doubt remained, the skilled artisan could confirm their belief simply by reading Claim 15. As the Examiner is undoubtedly aware, a dependent claim, by definition, incorporates all the limitations of the independent claim from which it depends. Accordingly, the Applicant respectfully submits dependent Claims 19 and 20 are not indefinite.

5. In response to the Examiner's rejection of Claims 15-20 for anticipation or, in the alternative, obviousness over WO 92/01477, the Applicant respectfully traverses. The sole independent claim of the present invention, 15, is directed to a delivery system having an active ingredient covalently bonded to a linker through a hydrolyzable covalent bond formed with a hydroxyl, CO<sub>2</sub>H, amino, mercapto, or enolizable carbonyl moiety of the active ingredient to

produce an ester, carboxylic acid, anhydride, amide, thioester, or enol ester; said linker being covalently bonded to a portion of subunits of a crosslinked polymer through a linker-polymer covalent bond selected from the group consisting of a nitrogen-carbon bond and a phosphorus-carbon bond.


The '477 reference, which discloses an excellent drug delivery vehicle, is directed primarily to a drug covalently bonded to a linker by reaction with a silyl functional group on the linker (or polymer) to form a silyl ether bond. '477 Reference, p. 9, lines 22-28. The '477 reference does not motivate a skilled artisan to prepare a drug delivery vehicle with the claimed covalent bonds between the active ingredient/linker and the linker/polymer. As a result, the present invention, as defined by the pending claims, provides polymeric site specific drug delivery systems with very different drug release performance characteristics.

The Applicant respectfully disagrees with the Examiner's assertion that the '477 reference discloses the C-N bond between the linker and the polymer. Rather, the '477 reference, on page 9, lines 14-22, reads, "[a] covalent bond can be formed between the active ingredient and such attached linker group . . . ." The '477 reference then discloses various bonds between the linker and the polymer and goes on to state that, "[s]ilyl ether covalent bonds are especially preferred . . . ." Further, the '477 does not, on page 10, disclose crosslinked polystyrene polymers with dialkylaminomethyl groups as the Examiner suggests. Rather, the '477 reference repeatedly identifies polybutadiene as a preferred polymer. Accordingly, the present invention is not anticipated or rendered obvious by the '477 reference.

Wherefore, for all the reasons set forth above, it is respectfully submitted that the art of record does not disclose or suggest the presently claimed invention. Accordingly, it is respectfully requested that the claims be allowed and the case passed to issue.

Applicant's undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our address given below.

Respectfully submitted,



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